# SOFTWARE REVIEW

of a MAJOR level of concern device

# PMA: P020033

DATE:     9/26/02

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SUBJECT:  Software review of Independence Technology's Independence IBOT 3000 Mobility System, Independence, a Johnson and Johnson company, 45 Technology Drive, Warren, New Jersey 07059, 908-412-2262. Contact person Susan Eichler-Huston.

## Succinct Conclusion:

The information contained within this submission is sufficient to meet the software concerns as described in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and it is recommended that, from a software standpoint, this submission be approved.

## SUMMARY:

This device is an advanced function wheelchair type device, using gyros for a dynamically stabilized system, to allow movement, not only on four wheels, but also on two wheels. This allows the user to raise and lower the chair=s height and to climb up stairs and over uneven terrain. The firm=s suggested description for a new regulatory class is Aa device that uses dynamic stabilization to provide multiple mobility functions, giving the user of the device access to a range of terrain and spaces. The functions provide mobility indoors, outside, including uneven and soft terrain, over obstacles, up inclines and up/down stairs. Operation at elevated height allows the user to interact with others and the environment at a standing level height. The device is customized based on the user=s functional capabilities and body characteristics@.

The active stabilization is accomplished by incorporating three elements: sensors that detect the orientation and rate of change in orientation of the device; motors that are capable of high power and high-speed servo operation; and embedded software which assimilates information from all of the sensors and motors and computes appropriate motor commands to achieve dynamic stability and implement the user=s commands.

1.    **Level of Concern**
      The firm provided their level of concern and the supporting rationale: **MAJOR.**

2.    **Software Description**
      The firm provided a comprehensive overview of the device features that are controlled by software, and a description of the intended operational environment.

3. **Device (including software) Hazard Analysis**
   The firm provided an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards.

4. **Design Specification**
   The firm provided an acceptable design specification document, which described what the program does and how it does it.

5. **Software Requirements Specifications (SRS)**
   The firm provided a copy of their software requirements specification document, which clearly documented their functional, performance, interface, design and development requirements.

6. **Traceability**
   The firm provided a traceability matrix, which provided the links between the hazards, requirements validation and testing.

7. **Validation (including verification and testing)**
   The firm provided an acceptable description of their systematic process of life cycle activities, including analysis, evaluation, assurance and testing of the software, and supporting documentation. This included a description of the activities and protocols at the unit, integration and system level, including pass/fail criteria, test reports, summaries and tests results.

8. **Architecture Design**
   The firm provided an acceptable description the software system partitioned into its functional subsystems including a description of the role that each module plays in fulfilling the software requirements.

9. **Development**
   The firm provided a summary of their software development life cycle plans describing the processes that have been put into place to manage the various software development life cycle activities. The firm included an annotated list of the control/baseline documents generated during the software development process, as well as the configuration management and maintenance plan.

10. **Revision Level History**
    The firm provided the revision history log, documenting all major changes to the software during its development cycle.

11. **Unresolved Anomalies (bugs)**
    The firm provided a list of all unresolved software anomalies, indicating the problem, the impact on device performance, and plans and time frames for correcting each problem.

12. **Release Version Number**
    The firm provided an acceptable description of the version numbers and dates.

# RECOMMENDATION:

The firm has provided acceptable documentation demonstrating that they have developed the software for this device under an appropriate software development program; that they have performed a hazard analysis from both the patient's and user's standpoint, and addressed those hazards; and carried out an appropriate validation process. These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other way. It is recommended that from a software standpoint this submission be approved.